

RECEIVED

From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

NASSIF, Omar A.  
Gowling Lafleur Henderson LLP  
Suite 4900  
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Toronto, Ontario M5L 1J3  
CANADA

PCT

GOWLING LAFLEUR HENDERSON  
PATENT DEPARTMENT

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT  
(PCT Rule 71.1)

Date of mailing  
(day/month/year) 15.11.2000

Applicant's or agent's file reference  
T8463747WO

## IMPORTANT NOTIFICATION

International application No.  
PCT/CA99/00694

International filing date (day/month/year)  
29/07/1999

Priority date (day/month/year)  
31/07/1998

Applicant  
NOVO RPS ULC et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

## 4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/



European Patent Office  
D-80298 Munich  
Tel. +49 89 2399 - 0 Tx: 523656 epmu d  
Fax: +49 89 2399 - 4465

Authorized officer

Edel. M

Tel. +49 89 2399-2426



REC'D 17 NOV 2000

WIPO

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference T8463747WO	<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/CA99/00694	International filing date (day/month/year) 29/07/1999	Priority date (day/month/year) 31/07/1998
International Patent Classification (IPC) or national classification and IPC A61F2/06		
Applicant NOVO RPS ULC et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.



2. This REPORT consists of a total of 6 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 4 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand  29/02/2000	Date of completion of this report  15.11.2000
Name and mailing address of the international preliminary examining authority:   European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer  Hooper, M  Telephone No. +49 89 2399 7438  

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA99/00694

## I. Basis of the report

1. This report has been drawn on the basis of *(substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments (Rules 70.16 and 70.17).):*

### Description, pages:

1-16 as originally filed

### Claims, No.:

1-24 with telefax of 23/08/2000

### Drawings, sheets:

1/3-3/3 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: . which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description. pages:
- ☐ the claims. Nos.:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/CA99/00694

☐ the drawings. sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	1-24
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-16
	No:	Claims	17-24
Industrial applicability (IA)	Yes:	Claims	1-24
	No:	Claims	

2. Citations and explanations  
**see separate sheet**

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:  
**see separate sheet**

**Re Item V**

1. Reference is made to the following documents.

D1: EP-A-0 689 805

D2: US-A-5 776 161

2. The application meets the requirements of Article 33(2) PCT and 33(3) PCT, as the subject-matter of claims 1-16 is considered novel and as comprising an inventive step when compared with the available prior art. The reasons are as follows.

- 2.1. Documents D1 and D2 show (see D1, figures, and D2, figures) an unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon.

Hence they do not show that the stent is to undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5mm. Hence the subject-matter is considered new, Article 33(2) PCT.

- 2.2. The technical problem to be solved by the invention can be considered as providing a stent which can be used for very small blood vessels. By having the maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5mm the stent can safely be used for such a purpose. None of the documents available show such a construction nor do they imply it.

Hence the subject-matter of claim 1 is considered as involving an inventive step, Article 33(3) PCT.

- 2.3. The same arguments apply for the subject-matter of claim 10, which differs from the subject-matter of claim 1 only in that a partially expanded stent is claimed. As the stents shown in D1 and D2 can be partially expanded too, the same documents are to be used when considering novelty and inventive step. And as the subject-matter of claim 10 comprises the same special technical feature of

claim 1, the same arguments concerning novelty and inventive step as stated for claim 1 apply *mutatis mutandis*.

3. As claims 2-9 and 11-13 are directly dependent on claims 1 and 10, and as claims 14-16 are *de facto* dependent on claim 10 the subject-matter of these claims is also considered both novel and inventive, Articles 33(2) and (3) PCT.
4. The subject-matter of claims 17-24 does not include an inventive step, Article 33(3) PCT. The only difference between the claimed subject-matter and standard practice as acknowledged by the applicant amounts to the stent being expanded before being placed onto a catheter, onto which it is to be, say, crimped (see claim 24). No technical effect results from this operation, and it is a step that would be obvious to any person wishing to slip a small tubular object onto a slightly larger tubular object. Hence no inventive step, Article 33(3) PCT, appears to be involved.

The dependent claims 18-24 add nothing to the claims they depend upon that would render the claims novel and inventive. All the suggested steps are only minor changes that a person skilled in the art would effect without exercising any inventive skill.

**Re Item VII**

1. Independent claims 1 and 10 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would have been appropriate, with those features known in combination from the prior art, e.g. document D1, being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).
2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).
3. The units of measure "inch" employed on page 12 in line 6 is not additionally expressed in terms of the units stipulated by Rule 10.1(a) PCT.
4. Some regional and national offices, e.g. the EPO, do not allow the incorporation by reference of other documents (be they published or not), as is done on page 3

in line 5 and on page 11 in line 20 of the application. Should the application enter the regional phase before the EPO it will become necessary to replace such statements with the specific inclusion of the subject-matter of relevance to the application.

-17-

What is claimed is:

1. An unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon to undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.
2. The unexpanded stent defined in claim 1, wherein the stent is expandable: from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation; and from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.
3. The unexpanded stent defined in claim 2, wherein, in the second pre-expanded position, the stent has a diameter greater than about 1.1 mm.
4. The unexpanded stent defined in any one of claims 2-3, wherein, in the second pre-expanded position, the stent has a diameter sufficiently large for the stent to receive expansion means to further expand the stent.
5. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter less than or equal to about 1.1 mm.
6. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about to about 1.1 mm.



-18-

7. The unexpanded stent defined in any one of claims 2-4, wherein, in the first unexpanded position, the stent has a diameter in the range of from about 0.5 to about 1.0 mm.

8. The unexpanded stent defined in any one of claims 1-7, wherein the tubular wall has a substantially circular cross-section.

9. The unexpanded stent defined in any one of claims 1-8, wherein the tubular wall is constructed of a plastically deformable material.

10. A partially expanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent:

having been expanded by the application of a radially outward force thereon from a first unexpanded position to a second pre-expanded position at which the stent has reached a point of plastic deformation, and

being further expandable upon the application of a radially outward force thereon from the second pre-expanded position to a third expanded position wherein the stent will undergo plastic deformation to a maximum yield point when the tubular wall has a diameter of less than or equal to about 3.5 mm.

11. The partially expanded stent defined in claim 10, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter of less than or equal to about 3.3 mm.

12. The partially expanded stent defined in claim 10, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.2 to about 3.3 mm.

-19-

13. The partially expanded stent defined in claim 10, wherein, in the third expanded position of the stent, the maximum yield point is reached when the tubular wall has a diameter in the range of from about 2.5 to about 3.0 mm.

5 14. A stent delivery kit comprising:  
a catheter;  
an expandable member disposed on the catheter; and  
the partially expanded stent defined in any one of claims 10-13 disposed  
on the catheter

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15. The stent delivery kit defined in claim 14, wherein the stent is mechanically mounted on the expandable member.

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16. The stent delivery kit defined in claim 15, wherein the stent is crimped onto the expandable member.

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17. A method for mounting an unexpanded stent on a catheter having an expandable member disposed thereon, the unexpanded stent comprising a proximal end and a distal end in communication with one another, a tubular wall disposed between the proximal end and the distal end, the tubular wall having a longitudinal axis and a porous surface defined by a plurality of interconnecting struts, the stent being expandable upon the application of a radially outward force thereon:

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(i) expanding the unexpanded stent to a second pre-expanded position at which the stent has reached a point of plastic deformation to produce a partially expanded stent; and

(ii) placing the partially expanded stent on the expandable member of the catheter.

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18. The method defined in claim 17, wherein Step (i) comprises urging the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

-20-

19. The method defined in claim 17, wherein Step (i) comprises pushing the stent over a mandrel in a direction substantially parallel to the longitudinal axis.

20. The method defined in claim 17, wherein Step (i) comprises pulling the  
5 stent over a mandrel in a direction substantially parallel to the longitudinal axis.

21. The method defined in any one of claims 19-20, wherein the mandrel is tapered.

10 22. The method defined in claim 17, wherein Step (i) comprises urging the stent over a die in a direction substantially parallel to the longitudinal axis.

23. The method defined in claim 17, wherein Step (i) comprises placing the stent over an expandable means, and thereafter expanding the stent to the second  
15 pre-expanded position.

24. The method defined in any one of claims 17-23, wherein Step (ii) comprises crimping the partially expanded stent on to the expandable member of the catheter.

## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Assistant Commissioner for Patents  
United States Patent and Trademark  
Office  
Box PCT  
Washington, D.C.20231  
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year)  
10 April 2000 (10.04.00)

International application No.  
PCT/CA99/00694

Applicant's or agent's file reference  
T8463747WO

International filing date (day/month/year)  
29 July 1999 (29.07.99)

Priority date (day/month/year)  
31 July 1998 (31.07.98)

## Applicant

RICCI, Donald, R. et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International Preliminary Examining Authority on:

29 February 2000 (29.02.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740 14 35

Authorized officer

Juan Cruz

Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

PCT

NOTIFICATION OF THE RECORDING  
OF A CHANGE(PCT Rule 92bis.1 and  
Administrative Instructions, Section 422)

From the INTERNATIONAL BUREAU

To:

NASSIF, Omar, A.  
Gowling Lafleur Henderson LLP  
Suite 4900  
Commerce Court West  
Toronto, Ontario M5L 1J3  
CANADA

<b>Date of mailing</b> (day/month/year) 23 August 2000 (23.08.00)	<b>IMPORTANT NOTIFICATION</b>
<b>Applicant's or agent's file reference</b> T8463747WO	
<b>International application No.</b> PCT/CA99/00694	<b>International filing date</b> (day/month/year) 29 July 1999 (29.07.99)

<b>1. The following indications appeared on record concerning:</b> <input type="checkbox"/> the applicant <input type="checkbox"/> the inventor <input checked="" type="checkbox"/> the agent <input type="checkbox"/> the common representative		
<b>Name and Address</b> NASSIF, Omar, A. Gowling, Strathy & Henderson Suite 4900 Commerce Court West Toronto, Ontario M5L 1J3 Canada	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b> 416-862-5775	
	<b>Facsimile No.</b> 416-862-7661	
	<b>Teleprinter No.</b>	
<b>2. The International Bureau hereby notifies the applicant that the following change has been recorded concerning:</b> <input type="checkbox"/> the person <input checked="" type="checkbox"/> the name <input type="checkbox"/> the address <input type="checkbox"/> the nationality <input type="checkbox"/> the residence		
<b>Name and Address</b> NASSIF, Omar, A. Gowling Lafleur Henderson LLP Suite 4900 Commerce Court West Toronto, Ontario M5L 1J3 Canada	<b>State of Nationality</b>	<b>State of Residence</b>
	<b>Telephone No.</b> 416-862-5775	
	<b>Facsimile No.</b> 416-862-7661	
	<b>Teleprinter No.</b>	
<b>3. Further observations, if necessary:</b>		
<b>4. A copy of this notification has been sent to:</b> <div style="display: flex; justify-content: space-between;"> <div> <input checked="" type="checkbox"/> the receiving Office  <input type="checkbox"/> the International Searching Authority  <input checked="" type="checkbox"/> the International Preliminary Examining Authority         </div> <div> <input type="checkbox"/> the designated Offices concerned  <input checked="" type="checkbox"/> the elected Offices concerned  <input type="checkbox"/> other:         </div> </div>		

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland  Facsimile No.: (41-22) 740.14.35	<b>Authorized officer</b>  I. Britel  Telephone No.: (41-22) 338.83.38
--	--

OCT 29 1999

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

GOWLING, STRATHY & HENDERSON  
Attn. NASSIF, Omar A.  
Suite 4900  
Commerce Court West  
Toronto, Ontario M5L 1J3  
CANADA

GOWLING, STRATHY & HENDERSON  
PATENT ATTORNEYS

NOTIFICATION OF TRANSMITTAL OF  
THE INTERNATIONAL SEARCH REPORT  
OR THE DECLARATION

(PCT Rule 44.1)

Date of mailing  
(day/month/year)

26/10/1999

Applicant's or agent's file reference

T8463747W0

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/CA 99/00694

International filing date  
(day/month/year)

29/07/1999

Applicant

NOVO RPS ULC et al.

1. ☒ The applicant is hereby notified that the International Search Report has been established and is transmitted herewith.

**Filing of amendments and statement under Article 19:**

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

**When?** The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

**Where?** Directly to the International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland  
Facsimile No.: (41-22) 740.14.35

**For more detailed instructions,** see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no International Search Report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Marcel Van den Heuvel

## NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

### INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

#### What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

#### When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

#### Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

#### How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

#### What documents must/may accompany the amendments?

##### Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

## NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:  
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:  
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:  
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or  
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:  
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

### "Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

### Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

### Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.



## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>T8463747W0</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/CA 99/ 00694</b>	International filing date (day/month/year) <b>29/07/1999</b>	(Earliest) Priority Date (day/month/year) <b>31/07/1998</b>
Applicant <b>NOVO RPS ULC et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

**1. Basis of the report**

- a. With regard to the language, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.



the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international search was carried out on the basis of the sequence listing:



contained in the international application in written form.



filed together with the international application in computer readable form.



furnished subsequently to this Authority in written form.



furnished subsequently to this Authority in computer readable form.



the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.



the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ Certain claims were found unsearchable (See Box I).

3. ☐ Unity of invention is lacking (see Box II).

**4. With regard to the title,**

the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

**5. With regard to the abstract,**

the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

**6. The figure of the drawings to be published with the abstract is Figure No.**

as suggested by the applicant.



because the applicant failed to suggest a figure.



because this figure better characterizes the invention.

3

None of the figures.

# INTERNATIONAL SEARCH REPORT

National Application No.

T/CA 99/00694

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 7 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 7 A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	EP 0 689 805 A (CORVITA CORP) 3 January 1996 (1996-01-03) column 7, line 1 - line 18 column 7, line 38 - line 44 figures 1,3	1, 10, 18, 20, 24
A	US 5 776 161 A (GLOBERMAN OREN) 7 July 1998 (1998-07-07) column 8, line 5 - line 29 column 8, line 34 - line 42	1, 10, 18, 20, 24
A	US 5 749 851 A (WANG LIXIAO) 12 May 1998 (1998-05-12) column 4, line 35 - line 65 column 5, line 16 - line 27	1, 10, 18, 20, 24
	-/-	

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

\* Special categories of cited documents:

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

15 October 1999

Date of mailing of the international search report

26/10/1999

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## INTERNATIONAL SEARCH REPORT

International Application No.

PCT/CA 99/00694

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
P, A	DE 197 22 384 A (GFE GES FUER FORSCHUNG UND ENT) 3 December 1998 (1998-12-03) abstract column 3, line 6 - line 32	1, 10, 18, 20, 24

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

P.T/CA 99/00694

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0689805	A	03-01-1996	CA 2152662 A JP 8038519 A US 5755774 A	28-12-1995 13-02-1996 26-05-1998
US 5776161	A	07-07-1998	WO 9833546 A AU 1808197 A DE 29723905 U EP 0909198 A	06-08-1998 25-08-1998 10-06-1999 21-04-1999
US 5749851	A	12-05-1998	NONE	
DE 19722384	A	03-12-1998	AU 8107298 A WO 9853763 A EP 0944367 A	30-12-1998 03-12-1998 29-09-1999